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PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0099452-wsgs	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/09475	International filing date (day/month/year) 28/09/2000	Priority date (day/month/year) 04/10/1999
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant MERCK PATENT GMBH et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input checked="" type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input checked="" type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		

Date of submission of the demand 09/04/2001	Date of completion of this report 08.01.2002
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Nichogiannopoulou, A Telephone No. +49 89 2399 8054

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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-41 as originally filed

Claims, No.:

1-11 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

Sequence listing part of the description, pages:

1-3, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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the description, pages:

the claims, Nos.:

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

copy of the earlier application whose priority has been claimed.

translation of the earlier application whose priority has been claimed.

2. This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 11.

because:

the said international application, or the said claims Nos. 11 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

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- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. .
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- the written form has not been furnished or does not comply with the standard.
 - the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 2, 3, 5, 9-11
	No: Claims 1, 4, 6-8
Inventive step (IS)	Yes: Claims
	No: Claims 1-11
Industrial applicability (IA)	Yes: Claims
	No: Claims 1-11

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item II

Priority

1. The present application validly claims priority from 04.10.1999. Any documents cited in the International Search Report as P documents have therefore not been considered as comprised in the prior art relevant for the present application.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 11 -as far as it concerns *in vivo* methods- relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

D1: MIYAMOTO H ET AL: 'Molecular cloning of a novel mRNA sequence expressed in cleavage stage mouse embryos' MOLECULAR REPRODUCTION AND DEVELOPMENT, vol. 34, no. 1, January 1993 (1993-01), pages 1-7, XP000892775, cited in the application

2. **Novelty and Inventive step (Article 33(2) and (3) PCT)**

The present application discloses the molecular cloning of ANIC-BP1B, a splice

variant of ANIC-BP, a human calcium binding protein of unidentified function that was found upregulated in a rat model of head trauma. ANIC-BP1B further shares homology with the functionally unidentified gene MO25.

D1 discloses the molecular cloning of the mouse MO25 gene and the sequence of the encoded polypeptide (Fig. 4). The disclosed sequence has 92.3% identity with SEQ ID No:2 of the present application over its entire length. **D1** is thus detrimental to the novelty and inventive step of claims 1, 4, 6-8.

3. Inventive step (Article 33(3) PCT)

Due to the fact that no function has been established for ANIC-BP1B, the claimed sequences are not associated with any known technical effect. Accordingly, the only underlying technical problem that can be recognised is the provision of further DNA sequences encoding potentially calcium binding proteins. To establish inventive activity, the provision of a sequence must be justified by the technical purpose, i.e. by a hitherto unknown or unexpected technical effect, caused by those technical features which distinguish the claimed molecules from numerous other ones. Due to the absence of any disclosed function or technical effect, the provision of the present sequence amounts to nothing more than an arbitrary selection. Consequently, the claimed molecules as well as vectors, host cells, antibodies and methods (claims 1-11) are considered to lack an inventive step, pursuant to Article 33(3) PCT.

4. Industrial applicability (Article 33(4) PCT)

In so far as the present specification is completely silent with regard to the function of the ANIC-BP-1B sequences, the possible fields of application for the claimed protein and polynucleotides suggested in the specification are merely speculative. Thus it is questionable whether the claimed subject-matter actually meets the requirements set forth in Article 33(4) PCT.

Re Item VI

Certain documents cited

**INTERNATIONAL PRELIMINARY
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International application No. PCT/EP00/09475

1. Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 00 78947	28.12.2000	14.06.2000	22.06.1999

- 2. WO 00 78947 has been published after the filing date of the present application and does therefore not constitute prior art in the meaning of Rule 64(1)(b) PCT. Said document will, however become of relevance for novelty assessment should the application enter the European phase.**

Re Item VIII

Certain observations on the international application

- 1. The term "fragments and variants" used in claims 1 and 4 in the context of a polypeptide and a DNA molecule respectively, is too vague and lacks clarity in the sense of Article 6 PCT. It is furthermore noted that such an unclear term jeopardises the novelty said claims.**